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Mc MAHON
MEDICAL INCORPORATED

510(k) Summary K961105

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Product Name:

Trade Name. Skin Dose Monitor, may be abbreviated to SDM.
Common Name. Patient Dosimeter.
Classification Name. (To be entered by Dr. Ralph Shuping at FDA)

Legally marked device to which equivalence is being claimed:

In Vivo Dosimeter

Manufactured by:

Sun Nuclear Corp.
425-A Pineda Court
Melbourne,
Florida 32940-7508

Description of the Skin Dose Monitor

The Skin Dose Monitor consists of the model 104-101 Instrument complete with couch mounting bracket and QA Test Box. The 104-120 limited re-use sensor is also part of the system.

The sensor consists of a scintillating crystal which partially converts absorbed ionizing radiation into visible light. A length of radio translucent optical fiber transports the emitted light to the 104-101 instrument. The light is converted to an electrical current within the instrument and following scaling and integrating, is displayed on an LCD display in Grays or Rads. The instrument is battery powered and the displayed reading is retained when power is switched off.

Intended use of the Skin Dose Monitor

The Skin Dose Monitor is designed to measure skin dose during X-Ray diagnostic and interventional procedures.

Comparison of technical features with those of the predicate device.

The differences between the Skin Dose Monitor (SDM) and the In Vivo Dosimeter (IVD) are due to the former being used during X-Ray diagnosis and the latter product being used during Radiation Therapy. Both have a skin mounted sensor, in the case of the SDM this is a crystal where the IVD uses a diode. Both are optimized for the radiation energy being measured. In the case of SDM the manufacturer provides a means of fixation of the sensor to the patients skin where the IVD manufacturer leaves this matter to user innovation.
Coupling to the processing and display instrument is by optical fiber for the Skin Dose Monitor and by cable for the IVD. The optical fiber was selected for its radio translucent qualities but provides an incidental advantage of total electrical isolation of the patient from the main instrument.
The SDM, which is designed for couch mounting is small, compact and robust. It is powered by batteries and has the minimum of intrusive user controls. The IVD which is intended for mounting remote from the patient includes a number of software based functions to aid data logging, etc., and is mains powered raising added safety issues.

None Clinical Performance assessment.

Extensive measurements have been carried out to ensure the SDM neither generates Electromagnetic Radiation, or is affected by levels of electromagnetic radiation found in the typical radiological examination room. Comparisons have been made with industry standard Ion chamber and diode dose measuring systems to confirm the skin dose monitor precision and stability are sufficient for its intended use. These include energy and dose rate response, and long term stability with expected changes in ambient temperature. Although as is the case with the IVD precision of 1% could be achieved with careful local physics calibration 10% is considered acceptable for skin dose monitoring and attempts to achieve further improvements at the cost of user convenience are not seen as justified.

Clinical Performance Assessment.

This has been restricted to confirming the effectiveness and safety of the adhesive fixing disc.
The sensor was fixed for prolonged periods to a number of volunteers. It was inspected for adhesion prior to removal, ease of removal was noted along with any skin discoloration. These tests confirmed those carried out by the material manufacturer, in that the sensor was adequately held in place for a number of hours, could be removed without undue discomfort and showed no signs of causing skin irritation.

Conclusions drawn from clinical and non-clinical tests.

The tests carried out were designed to confirm that differences between the Skin Dose Monitor and the predicate device, The In Vivo Dosimeter, would not compromise safety or effectiveness.

The main differences are explained by the intended use being for diagnostic rather than therapy dose monitoring. They were shown to enhance the effectiveness for the intended application and provide added user convenience.

The SDM design was also shown to have significant safety advantages.